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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/978,167	10/17/2001	Chunhua Yan	CL001303	3910

25748 7590 04/06/2004

CELERA GENOMICS CORP.
ATTN: WAYNE MONTGOMERY, VICE PRES, INTEL PROPERTY
45 WEST GUDE DRIVE
C2-4#20
ROCKVILLE, MD 20850

EXAMINER

STEADMAN, DAVID J

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 04/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/978,167	Applicant(s) YAN ET AL.	
	Examiner David J Steadman	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4,8,9 and 24-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4,8,9 and 24-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>10/20/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

- [1] Claims 4, 8-9, and 24-37 are pending in the application.
- [2] Applicants' amendment to the claims, filed March 03, 2004, is acknowledged. This listing of the claims replaces all prior versions and listings of the claims.
- [3] Applicants' amendment to the specification, filed March 03, 2004, is acknowledged.
- [4] Receipt of a substitute sequence listing in computer readable form and a paper copy thereof a statement of their sameness, and a statement that no new matter has been introduced in the specification, all filed March 03, 2004, is acknowledged.
- [5] Receipt of replacement formal drawings, filed March 03, 2004, is acknowledged.
- [6] Receipt of an information disclosure statement (IDS) filed October 20, 2003 is acknowledged. The examiner has considered all of the cited references and a copy of the IDS is attached to the instant Office action.
- [7] Applicants' arguments filed on March 03, 2003, 2004 have been fully considered and are deemed to be persuasive to overcome some of the rejections and/or objections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.
- [8] The text of those sections of Title 35, U.S. Code not included in the instant action can be found in a prior Office action.

Sequence Compliance

[9] In view of applicants' amendment to identify sequences in Figures 2A-2B and 3BB-3FF by sequence identifiers, the objection to the specification as not being sequence compliant (as set forth in item [4] of the Office action mailed November 23 2003) is withdrawn.

Specification/Informalities

[10] In view of applicants' amendment to the specification, the objection to the specification for referencing a hyperlink (as set forth in item [5] of the Office action mailed November 03, 2003) is withdrawn.

[11] The objection to the specification as failing to properly identify the drawings (as set forth in item [6] of the Office action mailed November 23, 2003) is maintained for the reasons stated below.

Applicants argue the "Description of the Figure Sheets" has been amended to more accurately identify the drawings. Applicants' argument is not found persuasive as the amendment to Figure 3 states, "FIGURES A-3FF". It is suggested that, for example, applicants properly label Figure 3 as "FIGURES 3A-3FF". Appropriate correction is required.

Claim Objections

[12] Claim 25 is objected to in the recitation of "of-SEQ ID NO:1". It is suggested that, for example, applicants amend the claim to remove the presence of the hyphen between "of" and "SEQ ID NO:1". Appropriate correction is required.

Claim Rejections - 35 USC § 101

[13] The rejection of claims 4, 8-9, and 24-37 under 35 U.S.C. 101 is maintained for the reasons of record (as set forth in item [7] of the Office action mailed November 23, 2003) and for the reasons stated below.

Applicants argue that nephronectins are supported by specific and substantial utilities related to the treatment and/or diagnosis of developmental disorders, as supported by the specification (citing page 3) and the art (citing the reference of Brandenberger et al., which was made of record in the Office action mailed November 23, 2003). Applicants argue that although Brandenberger et al. acknowledge that the mechanism by which nephronectin functions in conjunction with $\alpha 8\beta 1$ and the mechanism by which $\alpha 8\beta 1$ functions in kidney development may not be well understood, the mechanism by which an invention operates does not determine patentability. Applicants argue that the key to the utility of a compound that is effective for treating a disease is the end result, not the mechanism by which the compound achieves this result. Applicants argue that even if a putative mechanism of action is agreed upon, this may not be the actual mechanism. Applicants argue that the results of Brandenberger et al. establish that $\alpha 8\beta 1$ is involved in kidney development and the results of Brandenberger indicate that nephronectin is a ligand that mediates $\alpha 8\beta 1$ function in the kidney, citing quotations of Brandenberger et al. in support of their argument. Applicants argue that nephronectin has been linked to specific aspects of kidney development and that a skilled artisan would therefore recognize that the

claimed invention has specific and substantial utilities related to developmental disorders, particularly those of the kidney. Applicants' argument is not found persuasive.

Regarding applicants' argument that the mechanism by which an invention operates does not determine patentability, it is noted that the examiner has not required applicants to provide the mechanism by which nephronectin functions in conjunction with $\alpha 8\beta 1$. Moreover, the examiner has not questioned the results of Brandenberger et al., i.e., $\alpha 8\beta 1$ is involved in mouse kidney development and nephronectin as a ligand for $\alpha 8\beta 1$ in mice. While the mechanism by which nephronectin interacts with $\alpha 8\beta 1$ is certainly not required to satisfy the utility requirement of 35 USC 101, it is the examiner's position that further experimentation is required to identify a "real-world" use for the claimed invention. The specification asserts "novel human nephronectin splice forms are particularly useful as therapeutic targets for treating developmental disorders" (page 3) and applicants assert "the nephronectin encoded by the claimed polynucleotides are supported by specific and substantial utilities related to the treatment (and/or diagnosis) of developmental disorders" (page 9, bottom of the response filed March 03, 2004). However, the asserted use of the claimed nucleic acid as a therapeutic target and for treatment and/or diagnosis of developmental disorders is not substantial as further experimentation is required for such use, at least for the following reasons. First, it is noted that, while the claimed polynucleotides encode polypeptides that share sequence identity with nephronectins from mice, there is no indication in the specification that the claimed nucleic acids encode biologically active polypeptides. Thus, as stated in a previous Office action, it is just as likely that the

polypeptides encoded by the claimed polynucleotides are biologically inactive. Thus, further experimentation would be required to determine whether the encoded polypeptides are biologically active and have the ability to interact with $\alpha 8\beta 1$. Even assuming arguendo there was evidence to suggest that the encoded polypeptides are biologically active and have the ability to interact with $\alpha 8\beta 1$ – which there is not – it is noted that neither the specification nor the prior art provides guidance as to the biological significance of the interaction of nephronectin with $\alpha 8\beta 1$. Such guidance is necessary in order for one to use the claimed polynucleotide as a therapeutic and/or diagnostic agent. Brandenberger et al. was cited in a previous Office action to support the examiner's argument that, because of the lack of understanding of the biological significance of the nephronectin- $\alpha 8\beta 1$ interaction, a skilled artisan would be required to perform further experimentation to identify a "real world" context of use for the claimed polynucleotide. Even assuming arguendo the evidence of record provided guidance regarding the biological significance of the nephronectin- $\alpha 8\beta 1$ interaction, it is noted that there is no indication in the specification or the prior art that the claimed polynucleotide can be used for therapeutic or diagnostic purposes and neither the specification nor the prior art provides the necessary guidance for using the claimed polynucleotide for such purposes. Consequently, the asserted utilities for the claimed polynucleotide for treatment and/or diagnosis of developmental disorders are not specific and substantial.

Claim Rejections - 35 USC § 112, Second Paragraph

[14] In view of applicants' amendment, the rejection of claims 25 and 27 under 35 U.S.C. 112, second paragraph, (as set forth in item [8] of the Office action mailed November 23, 2003) is withdrawn.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

[15] Claims 4, 8-9, and 24-37 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth in item [13] above, one skilled in the art clearly would not know how to use the claimed invention. It is noted that the examiner intended to raise the instant rejection, in accordance with MPEP 2107 ("[a] deficiency under 35 U.S.C. 101 also creates a deficiency under 35 U.S.C. 112, first paragraph") in the Office action mailed November 23, 2003. However, due to an editing error, the rejection was inadvertently omitted. Thus, the rejection is being raised in the instant Office action.

Conclusion

[16] Status of the claims:

- Claims 4, 8-9, and 24-37 are pending.

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- Claims 4, 8-9, and 24-37 are rejected.
- No claim is in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The Examiner can normally be reached Monday-Friday from 7:00 am to 5:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX number for submission of official papers to Group 1600 is (703) 308-4242. Draft or informal FAX communications should be directed to (703) 746-5078. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman

Patent Examiner

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[Signature]
2004-01-04